

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF OHIO
EASTERN DIVISION

IN RE NATIONAL PRESCRIPTION

OPIATE LITIGATION

This document relates to:

Track One Cases

MDL 2804

Case No. 17-md-2804

Hon. Dan Aaron Polster

**REPLY IN SUPPORT OF PLAINTIFFS' OMNIBUS MOTION
IN LIMINE (DKT. #2652) AND MEMORANDUM IN SUPPORT**

October 14, 2019

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Plaintiffs file this Reply in support of their Omnibus Motion *in Limine* to address certain specific points raised by Defendants in their response. In the interests of brevity and judicial efficiency, Plaintiffs will not reiterate the facts, law, and argument set forth in their Motion, but instead incorporate them by reference as if fully set forth herein. *See* Dkt. #2652. The Court should not interpret Plaintiffs' lack of a response to a particular point as conceding that Defendants' arguments are correct, but instead as an acknowledgement that Plaintiffs' Motion adequately stated the reason for the MIL and nothing further needs to be argued.

GENERAL LIMINE REQUESTS (NON-CASE-SPECIFIC)

1. **Any reference to the parties' attorneys' fee arrangement or how litigation expenses are paid, or how much those expenses are, in connection with this or any similar litigation.**

Defendants concede that the substance of this MIL is appropriate; their only complaint is Plaintiffs' refusal to accede to added language seeking to preclude counsel from "suggest[ing] that they are handling the case for personal or altruistic reasons." Dkt. #2725 at pp. 1-2. Plaintiffs would not agree to this added language because it is overly broad and vague, making it practically unenforceable. To the extent Defendants are seeking to prevent Plaintiffs' counsel from claiming that they are handling this case for free, Plaintiffs' counsel have no intention of making any such statement. But the language proposed by Defendants is significantly broader than that. They provide no legal authority justifying such a broad request.

2. **Any reference to how, when, or under what circumstances, the parties selected or hired their attorneys, or to any referral arrangements or other counsel the parties may have retained or consulted beyond their current counsel.**

Plaintiffs accept that Defendants may inquire as to *when* Plaintiffs hired their attorneys.¹ However, the *circumstances* under which Plaintiffs retained counsel are not germane to Defendants'

¹ Plaintiffs proposed the following compromise language for this MIL, but Defendants rejected it: "Any reference to how, ~~when~~, or under what circumstances the Parties selected or hired their attorneys, to any referral arrangements or other counsel the Parties may have retained or consulted beyond their current counsel."

statute of limitations, or any other, defense. *See, e.g., In re: Tylenol (Acetaminophen) Mktg.*, Civil Action No. 12-cv-07263, 2016 WL 3125428, at *5-6, *17 (E.D. Pa. June 3, 2016). But even if such evidence was relevant, this information is protected under the attorney-client privilege and Defendants have failed to justify disclosure. It is well-established that the attorney-client privilege attaches at the initial inquiry made to an attorney for legal advice. *See, e.g., Hilton-Rorar v. State & Fed. Commc'ns Inc.*, No. 5:09-CV-01004, 2010 WL 1486916, at *7 (N.D. Ohio Apr. 13, 2010) (“When a potential client consults with an attorney, the consultation establishes a relationship akin to that of an attorney and existing client” (quoting *Banner v. City of Flint*, 99 Fed. App’x 29, 36, 2004 WL 771672, at *6 (6th Cir. 2004))). The privileged communication between Plaintiffs and their counsel is permanently protected from disclosure unless the protection is waived. *Reed v. Baxter*, 134 F.3d 351, 355–56 (6th Cir. 1998) (internal citations omitted). At no time have Plaintiffs either expressly or impliedly waived this privilege.² Accordingly, evidence of how and under what circumstances Plaintiffs retained counsel should be excluded and Plaintiffs’ MIL No. 2 should be granted as modified below:

Any reference to how or under what circumstances, the parties selected or hired their attorneys, or to any referral arrangements or other counsel the parties may have retained or consulted beyond their current counsel.

3. Any reference to whether counsel generally represents plaintiffs or defendants, what type of law they practice, and how they obtain clients.

This MIL has been mooted by an agreed stipulation between the parties, as noted in Defendants’ response. Dkt. #2725 at p. 3.

² *See, e.g., SD3, LLC v. Black & Decker (U.S.), Inc.*, No. 114CV00191CMHIDD, 2016 WL 4722001, at *4 (E.D. Va. July 29, 2016) (finding the attorney-client privilege is not impliedly waived with regard to the statute of limitations issue when a party attempts to evade the statute of limitations by arguing fraudulent concealment if the party does not rely upon the privileged communication to prove its case); *cf. Beery v. Thomson Consumer Elecs., Inc.*, 218 F.R.D. 599, 604 (S.D. Ohio 2003) (finding attorney-client communication is only waived “when a party affirmatively uses privileged communications to defend against or attack the opposing party”).

4. **Any reference suggesting or in any way reflecting the financial status or resources of any of the attorneys representing the parties, or those attorneys' law firms, or any of those attorneys' other businesses or cases.**

This MIL has been mooted by an agreed stipulation between the parties, as noted in Defendants' response. Dkt. #2725 at p. 3.

5. **Any references to the accommodations of, or the use of private aircraft for transportation by, any witnesses, parties, or counsel.**

Defendants argue that the type of transportation and accommodations used by an expert during his or her work in this case is a proper subject of cross-examination because it constitutes supplemental compensation to the expert with "luxuries." Dkt. #2725 at p. 5. But they provide no legal authority that actually supports this argument.

As a preliminary matter, Defendants clearly cite *In re DePuy Orthopaedics, Inc., Pinnacle Hip Implant Prod. Liab. Litig.*, 888 F.3d 753 (5th Cir. 2018) in an effort to impugn the character of Plaintiffs' counsel and not because that case has any relevance to the matter at issue here. In *DePuy*, the issue was whether certain payments to experts and contributions to an expert's preferred charity were appropriately disclosed to the opposing party. *Id.* at 788. That case had nothing to do with the admissibility of an expert's hotel accommodations or private air travel.

Defendants claim that they "are entitled to cross-examine plaintiffs' experts about *all* of the compensation or reimbursement they receive for their work in these cases, not just the payments received on their invoices." Dkt. #2725 at pp. 4-5. In support, they cite *DePuy*, which as previously noted is not relevant here. The remaining cases cited by Defendants for this point, all of which are non-Ohio state court cases, are similarly inapposite as they all address the relevance of an expert's substantial monetary ties to a particular industry, or to one side of the bar, in order to demonstrate bias. *See Ray v. Draeger*, 353 P.3d 806, 814-16 (Alaska 2015) (evidence that an expert witness hired by the defense had a substantial connection to the insurance industry was relevant to the issue of bias); *Sears v. Rutishauser*, 466 N.E.2d 210, 211 (Ill. 1984) (trial court erred by not allowing defense counsel to cross-examine plaintiff's medical expert concerning the number and frequency of referrals the expert had received from plaintiff's attorney); *Brantley v. Sears Roebuck & Co.*, 959 S.W.2d 927, 929

(Mo. App. E. Dist. 1998) (evidence that expert “was regularly hired by Insurer,” “had worked on over one-hundred fifty cases for Insurer[,]” and was testifying in that case “so that Insurer might receive \$154,000 of its money back” was admissible to show bias).

Evidence regarding an expert’s hotel accommodations and private air travel in this case is too attenuated to show bias, as Judge O’Malley has explained:

Various fact and expert witnesses have used plaintiffs' counsel's private airplanes to attend depositions, hearings, medical appointments, and so on. Ruth seeks to preclude defendants from bringing out this information at trial, while defendants argue it is legitimate evidence of bias, in the same way as is evidence of an expert's hourly rates. *The Court concludes the “private airplane” evidence is too attenuated to show bias, so the motion is GRANTED.* Any impeachment on the basis of bias due to financial interests may be undertaken sufficiently by adducing evidence of how much a witness got paid, how often they have worked for a particular party (or type of party), and the extent to which their expenses were covered or reimbursed. *Federal Rules of Evidence 403 and 611 counsel against delving into greater detail regarding which hotels experts use, in what restaurants they ate, whether they fly first class, and so on.* This limitation will be applied equally to all parties.

Ruth v. A.O. Smith Corp., 1:04-CV-18912, 2006 WL 530388, at *6 (N.D. Ohio Feb. 27, 2006) (emphasis added). Presumably, Defendants can make the point that an expert’s travel expenses related to this case have been covered by Plaintiffs or their counsel without mentioning the use of a private plane or the name of the hotel in which the expert stayed.

The only cases Defendants cite that even mention private air travel provide no support for their argument and are factually inapposite.³ *In re Campbell*, 625 S.E.2d 233 (S.C. App. 2006), *aff’d as modified*, 666 S.E.2d 908 (S.C. 2008), involved a probate action in which a daughter sought to have herself appointed as conservator of her mother’s assets. *Id.* at 234. The probate court appointed two doctors to examine the mother’s capacity to handle her own affairs. *Id.* These doctors had long-standing relationships with the mother and had been previously designated by the mother as her expert witnesses for the conservatorship proceedings.⁴ After they testified that the mother was

³ Defendants cite no cases discussing the hotel accommodations of experts.

⁴ *Id.* at 235 (one doctor “admitted to being a friend of Mother’s for over sixty years, attending her husband’s most recent birthday party, and having supper with Mother four months prior to examining (footnote continues on next page)

competent to handle her own financial affairs, the probate court denied the daughter's request for conservatorship. *Id.* at 234. The appellate court reversed, finding these doctors were not disinterested *because the mother had previously designated them as experts.* *Id.* at 236 ("Here, Mother had previously designated Drs. Cathcat and Edwards as experts. Thus, it was a foregone conclusion those doctors would opine Mother was capable of handling her own financial affairs."). Although the court mentioned in the factual background of the opinion that the doctors had flown by private jet to the mother's home in order to conduct their examination (*id.* at 235), there is absolutely no indication that this was the basis of, or even relevant to, the appellate court's determination that the doctors were disinterested.

U.S. v. Mitrow, S3 13 CR. 633 PAE, 2015 WL 5245281 (S.D.N.Y. Sept. 8, 2015), is also inapposite. In that case, a criminal defendant pled guilty to conspiracy to commit wire fraud and tax evasion related to his fraudulent use of company funds to pay for his personal expenses, which included "travel by [the defendant] to resorts with his paramour, continuing an approximately nine-year (2001-2009) practice in which [the defendant] caused [the company] to pay for roughly monthly private jet trips with the paramour to hotels in Mexico, Hawaii, Aspen, Jackson Hole, Manila, and elsewhere." *Id.* at *2. The language quoted by Defendants in their response related to the court's discussion of the reasonableness of the company's policy against "pay[ing] for business travel on private jets." *Id.* at *6.

Finally, Defendants request that if the Court grants this MIL, it should also prohibit Plaintiffs from cross-examining defense experts on *all* issues related to bias. They provide no legal authority to support this ridiculous request. As discussed above, evidence regarding an expert's hotel accommodations and private air travel is irrelevant because it is too attenuated to show bias. But evidence that actually is relevant to an expert's bias should be fair game for cross-examination.

her"; second doctor "had also eaten supper with Mother four months prior to examining her and before that, she had occasionally consulted him from 1950 to 1995 if she was having medical problems").

6. **Any comment or reference to philanthropy or good deeds or acts carried out by the parties or their employees unrelated to opioid addiction prevention (*e.g., references to community service or charity work, or charitable donations made by Defendants or any of their employees, statements that Defendants are “good corporate citizens,” etc.*).**

By this MIL, Plaintiffs are seeking to preclude evidence of Defendants’ *unrelated* good acts or deeds. For example, if a Defendant had donated money to a cancer charity, or provided free vaccines to communities in Africa, this would clearly be irrelevant to any issue in this case. To address the concerns raised by Defendants in their response, Plaintiffs would agree to modify their MIL No. 6 to state as follows:

Any comment or reference to philanthropy or good deeds or acts carried out by the parties or their employees unrelated to opioids (*e.g., references to community service or charity work, or charitable donations made by Defendants or any of their employees, statements that Defendants are “good corporate citizens,” etc.*).

7. **Any reference to any alleged malpractice claims involving the parties’ designated experts.**

Defendants argue that it is possible that a malpractice claim involving a party’s expert may be relevant to that expert’s testimony. In order to address this concern, Plaintiffs would agree to modify their MIL No. 7 to exclude “any reference to any alleged malpractice claims involving the parties’ designated experts that are unrelated to opioids.”

8. **Any reference to experts not testifying in this litigation, experts retained in other cases, experts that were de-designated in this case, or any scientific or other discipline(s) for which no expert has been designated by the opposing party.**

Defendants fail to provide a legitimate reason for which counsel or witnesses could refer to the absence of particular experts or experts in particular fields. In particular, Defendants offer no basis to permit them to comment on the absence of experts in fields that are irrelevant to Plaintiffs’ claims, or to refer to experts retained in other cases. To the extent Defendants believe the absence of expert testimony on a particular subject is relevant, they should be required to raise the issue outside the hearing of the jury, so as not to prejudice the jury with references to experts without a showing that such expertise would be relevant. In addition, the parties should not be permitted to

refer to experts whose testimony or opinions the jury will not hear, including experts called in other cases, as such references are likely to be confusing.

9. **Use of any deposition video or associated technology that alters the appearance of what was displayed at the deposition, including but not limited to, the use of “highlighting,” enlarging, or otherwise emphasizing documents or portions of documents, unless the emphasis was done during the deposition and is part of the deposition video record.**

Defendants argue that Plaintiffs are seeking “to gain an unfair advantage to which they are not entitled” through their MIL No. 9. Dkt. #2725 at p. 9. Not so. Defendants admittedly *chose* to (i) take “the traditional approach in conducting depositions, questioning witnesses on a single video feed and handing them the documents to which they would be referring[,]” and (ii) “not carefully stage and record the projections of exhibits while taking depositions.” *Id.* at p. 11. They easily could have taken the same approach to depositions as Plaintiffs’ counsel, which is a perfectly legitimate and effective approach to conducting depositions. They chose not to. That they now regret this decision is no basis to allow them to alter the appearance of what was presented at the deposition. If anything, it is Defendants who are seeking to gain an unfair advantage by doing at trial what they could have done, but did not do, during the deposition. Finally, Defendants’ reference to *DePuy* is a red herring. The new trial ordered in that case had nothing to do with the district court’s granting of an identical MIL as the one proposed here.

10. **Any reference to unrelated personal matters of a party’s expert or the expert’s family, such as divorce proceedings, employment or other disputes, and any other unrelated matters.**

This MIL has been mooted by an agreed stipulation between the parties, as noted in Defendants’ response. Dkt. #2725 at p. 11.

11. **Any reference to the filing of the parties’ motions *in limine*, the contents thereof, or other such motions to exclude evidence and their contents, and any agreements or proceedings in connection with this motion or reference to any such matter.**

Defendants agree that references to motions *in limine* in front of the jury are inappropriate. Dkt. #2725 at p. 12. But they appear to want to broaden this MIL to preclude reference to any and

all evidentiary requests (formal and informal) and any and all stipulations concerning trial conduct or the exclusion of evidence, without providing any legal argument supporting their request. Defendants easily could have filed an affirmative motion *in limine* seeking this broad relief. They did not. They should not be permitted to do so through a response to Plaintiffs' MILs, especially when they have not met their burden in showing such evidence is clearly inadmissible on all potential grounds. Finally, Defendants raise a concern about how to phrase objections that refer to motions *in limine* or other motions to exclude evidence (*e.g.*, *Daubert* motions, etc.). Counsel can simply say "objection" and request a sidebar with the Court to address the matter outside the hearing of the jury.

12. Any suggestion or reference that an award of punitive damages is unconstitutional or illegal.

This MIL has been mooted by an agreed stipulation between the parties, as noted in Defendants' response. Dkt. #2725 at p. 12.

GENERAL LIMINE REQUESTS (CASE-SPECIFIC)

13. Any argument or suggestion that the Controlled Substances Act and its implementing regulations do not impose, or have not always imposed, on registrants an identification duty, reporting duty, and no-shipping duty with respect to suspicious orders.

Defendants' argument that they should be permitted to re-litigate the scope of their obligations under the CSA materially distorts and misrepresents this Court's August 19, 2019, ruling (Dkt. #2483) on this issue. In its August 19 ruling ("CSA Opinion"), this Court held:

[T]he Court concludes that the CSA statutory and regulatory duties to maintain effective controls against diversion includes a duty not to ship suspicious orders. Indeed, given the overriding duty of a registrant to maintain effective controls against diversion, the Court is hard-pressed to think of a more basic requirement than not to ship a dubious order bearing indicia that the drugs could be diverted to illegal channels. How can a registrant freely ship suspicious orders and still comply with its duty to maintain controls against diversion? It cannot. It has a duty not to ship the order unless due diligence reasonably dispels the suspicion.

Dkt. #2483 at pp. 18-19. In reaching this conclusion, the Court did not rely on evidence concerning DEA enforcement policies, *see id.* at p. 18 n.13, but rather on the language of the statute, the regulations, and court decisions construing them. The Court's ruling thus defines the scope of duties established by the statute and regulations *as a matter of law*. As neither the law nor the regulations have changed in the past thirty years, there is no basis for Defendants to argue that they have no duty to halt shipments, or that their legal duties have changed over time, such that the CSA and its regulations did not always impose this duty. Those arguments are precluded by the Court's decision.

What the Court recognized remains a disputed issue of fact pertains to how the DEA enforced the CSA, and whether Defendants complied with it, not what the law requires. Thus, in the CSA Opinion, the Court noted that "Cardinal asserts that, in 2007, the DEA changed its interpretation of the law and for the first time announced that submitting ILRs would not satisfy the suspicious order reporting requirement." Dkt. #2483 at p. 28. The Court concluded that "[t]he sum of evidence presented shows material facts in dispute that must be resolved by a jury." *Id.* Clearly, the facts that are in dispute pertain to how the DEA interpreted and enforced the CSA, not to what the law actually is. Similarly, the Court explained that "McKesson counters with evidence that during this time, the DEA accepted its SOMS and manner of reporting as compliant and the DEA did not impose a no-ship requirement" and concluded that "[t]hese facts present issues for a jury determination." *Id.* at 29. Again, it is clear that what remains in dispute is whether Defendants were permitted by the DEA to maintain suspicious order management programs that did not, in fact, comply with the meaning of the statute and regulations. To be clear, Plaintiffs do not agree that the DEA ever interpreted the law as Defendants contend, or that the DEA affirmatively permitted Defendants to maintain programs that did not comply with the law. But, to the extent Defendants contend DEA told them they did not need to halt or investigate suspicious orders, Plaintiffs agree that is a disputed issue of fact. That issue of fact, however, does not permit Defendants to re-open the legal question that has already been decided by this Court, as to what the CSA actually requires. Defendants ought not to be permitted to suggest to the jury that the CSA

means something different from what this Court has already decided it means, or that the meaning of the law has somehow shifted over time when the law has not changed during the relevant period.

Nor are Defendants correct that Plaintiffs' motion is "vague." Plaintiffs do not refer generally to Defendants' duties under the CSA, as Defendants would have it. Rather, Plaintiffs refer specifically to the "identification duty, reporting duty, and no-shipping duty." Dkt. #2652 at p. 10. These duties were defined by the Court in *Masters Pharmaceutical, Inc. v. DEA*, 861 F.3d 206 (D.C. Cir. 2017), and by this Court in its CSA Opinions. Dkt. #2483 at pp. 14-19. These are the duties Defendants ought not to be permitted to deny.

For these reasons, Plaintiffs' accurately worded motion *in limine*, which refers specifically to the legal duties imposed by the CSA, and its implementing regulations, should be granted in its entirety.

14. Any reference that tort laws frustrate the FDA's or DEA's regulatory policies, or to the potential impact on pharmaceutical companies, the FDA, or the DEA, if any, of permitting tort claims to be asserted or of allowing a plaintiff to prevail.

Defendants argue that Plaintiffs seek to prevent them from putting on their preemption defenses, but very little remains of those defenses and the purported frustration of FDA or DEA regulatory policies is not relevant to what does remain, or to any legitimate issue in the case. Nor do any of the preemption defenses that still exist present any question to be determined by a jury.

Defendants refer or allude to three different types of preemption without clearly distinguishing among them. These three types are (1) "obstacle" preemption; (2) "impossibility" preemption; and (3) *Buckman* preemption. "Obstacle" preemption arises when a state law action creates "an unacceptable obstacle to the accomplishment and execution of the full purposes and objectives of Congress." *Wyeth v. Levine*, 555 U.S. 555, 563-64 (2009). "Impossibility" preemption occurs when it is impossible for a defendant to comply with its state-law duties without violating federal law." *Id.* at 563. *Buckman* preemption precludes a plaintiff from relying on claims that arise solely from federal law (as to which there is no private right of action) or implicate a claim of fraud on the FDA; rather, a plaintiffs' claims must be grounded in traditional state law that imposes

obligations that may parallel, but not conflict with, federal law. *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 348-353 (2001).

Plaintiff's MIL seeks to preclude Defendants from “arguing or suggesting that tort laws frustrate the FDA’s or the DEA’s regulatory policies.” The only preemption doctrine implicated by arguments about the frustration of governmental policy is obstacle preemption. In *Wyeth*, however, the Supreme Court rejected, as a matter of law, the applicability of obstacle preemption to prescription drugs and FDA policy. The Court held that the federal Food Drug & Cosmetic Act was not intended to replace state-law tort remedies and that state law provides a complementary form of drug regulation. *See Wyeth*, 555 U.S. at 573-81; *see also In re Nat'l Prescription Opiate Litig.*, No. 1:17 MD 2804, 2019 WL 4178591, at *12 (N.D. Ohio Sept. 3, 2019) (“SJ Op.”) (rejecting obstacle preemption with respect to FDA and DEA); *In re Nat'l Prescription Opiate Litig.*, No. 1:18-OP-45090, 2018 WL 4895856, at *25 (N.D. Ohio Oct. 5, 2018) (“R&R”), *report and recommendation adopted in pertinent part*, No. 1:17-MD-2804, 2018 WL 6628898 (N.D. Ohio Dec. 19, 2018) (rejecting obstacle preemption). Moreover, it is clear from the discussion in *Wyeth* that the question of obstacle preemption – whether state law frustrates the purpose of Congress and so must give way – is a legal question for the court and relies on “interpretation of congressional intent and . . . an agency's power to pre-empt state law.” 555 U.S. at 573; *see also Merck Sharp & Dohme Corp. v. Albrecht*, 139 S. Ct. 1668, 1680 (2019) (factual questions that bear on preemption defense are to be decided by the court, not the jury). It is not up to the jury to decide if the laws at issue in this case are wise, comport with good policy, obstruct federal policy, will produce good outcomes, or will adversely affect pharmaceutical companies. The jury must apply the law as provided by the Court. There is no proper purpose for which Defendants can suggest that application of the law will produce undesirable outcomes. *See Tylenol*, 2016 WL 3125428, *8; *Georges v. Novartis Pharm. Corp.*, CV 06-05207, 2013 WL 5217198, *5 (C.D. Cal. Apr. 4, 2013); *In re Vioxx Products Liab. Litig.*, MDL 1657, 2005 WL 3164251, *1 (E.D. La. Nov. 18, 2005).

Impossibility preemption is quite distinct from obstacle preemption, because it requires defendants to identify an actual conflict between state and federal law such that compliance with the

former would require them to violate the latter. In this context, Plaintiffs note that, under *Wyeth* and *Albrecht*, claims that a branded manufacturer ought to have changed the label for its drug are *not* preempted unless there is “there is clear evidence that the FDA would not have approved the warning that state law requires.” *Albrecht*, 139 S. Ct. at 1676, *quoting Wyeth*, 555 U.S. at 571. Defendants do not attempt to, and cannot, show that this is the case, *see* SJ Op., 2019 WL 4178591, at *5 (no evidence that FDA approved Defendants’ fraudulent marketing campaign); R&R, 2018 WL 4895856, at *23 (Defendants failed to show Plaintiffs’ claims are preempted), but, even if they did, the law is now settled that the question whether the FDA would have approved or disapproved a particular warning is to be decided by the court, and not by a jury. *Albrecht*, 139 S. Ct. at 1680. Thus, even if Defendants do seek to show, as a matter of fact, that a particular label change would not have been approved, there would never be a reason for them to argue or suggest, before the jury, that any of Plaintiffs’ claims would frustrate agency policies.

As Defendants note, generic manufacturers may assert the duty of “sameness,” which requires them to maintain labels identical to that of equivalent branded drug, as a potential basis for impossibility preemption. Dkt. #2725 at p. 15.⁵ This Court has already held that Plaintiffs’ claims do not implicate this duty. *See* SJ Op., 2019 WL 4178591, at *6. And even if that were not the case, this issue presents no reason for the jury to consider whether the enforcement of state law will frustrate any *policy* of the FDA (or the DEA). Impossibility preemption does not concern itself with federal *policies*, but rather with federal *law*. Only when the tort duty in question would require the defendant to violate an actual federal law (whether statutory or regulatory) does compliance with both state and federal law become impossible. And because impossibility preemption is a legal question for the court, even when it encompasses factual disputes, *see Albrecht*, 139 U.S. at 1680, any references to it ought to be made outside the hearing of the jury.

⁵ How the duty of sameness operates when the generic manufacturer is also the branded manufacturer complicates the question in this case, but while that issue may present legal questions for the Court, it provides no basis for Defendants to present arguments or suggestions to the jury about the impact of tort law on federal policy or regulation.

Finally, Defendants seek to invoke *Buckman* preemption. They recognize, as they must, that Plaintiffs have repeatedly disavowed any claim of fraud on the FDA or the DEA. Dkt. #2725 at p. 15; *see also* SJ Op., 2019 WL 4178591, at *12 (“Plaintiffs have not alleged a claim for fraud on a federal agency”). Yet, they contend that the Court should disregard these disavowals, suggesting that Plaintiffs may “attempt to prove their claims by reference to allegedly fraudulent statements made by defendants to the DEA,” and that, if that occurs, defendants should be permitted to “respond appropriately to establish that plaintiffs cannot satisfy their burden merely by demonstrating a fraud on the DEA.” *Id.* at 15-16. Of course, the mere reference to statements to the DEA that may have been fraudulent does not mean that Plaintiffs are trying a “fraud on the DEA” claim. This is especially true because among the predicate acts for Plaintiffs’ *federal* RICO claim are violations of 21 U.S.C. § 843(a)(4)(A), which makes it unlawful to “furnish false or fraudulent material information in, or omit any material information from, any application, report, record, or other document required to be made, kept or filed under the [CSA].” In order to establish predicate acts under these sections, Plaintiffs will be required to show that Defendants made fraudulent statements to the DEA, but because of the incorporation of violations of the CSA into the RICO statute, *see* 18 U.S.C. § 1961(1), there is no issue of preemption connected with such proof. That is, Plaintiffs do not seek to create what is, in essence, a “fraud on the DEA” claim that Congress has not already created, which is what *Buckman* precludes. More importantly, however, it is not for Defendants to tell the jury how Plaintiffs may satisfy their burden and whether fraud on the DEA, alone, is sufficient to establish any RICO predicate act. That is the Court’s job. And even if Defendants were to suggest that Plaintiffs have not met their burden simply by establishing fraud on the DEA, that has nothing whatsoever to do with what Plaintiffs seek to exclude in this particular motion -- references that tort laws frustrate the FDA’s or DEA’s regulatory policies or the potential impact on pharmaceutical companies, the FDA, or the DEA, if any, of permitting tort claims to be asserted or of allowing a plaintiff to prevail. Defendants fail to show that there is or can be any legitimate reason for them to make such references or suggestions. This MIL should be granted in its entirety.

15. Any reference to the DEA “approving” or “endorsing” a particular Defendant’s SOM program.

Plaintiffs explained at length in their Motion why evidence of purported DEA “approvals” and “endorsements” of a particular Defendant’s SOM program is irrelevant and unfairly prejudicial in this case. Dkt. #2652 at pp. 12-20. Plaintiffs will not reiterate these arguments here, but instead will address several points raised by Defendants in their response.

First, Defendants state that the “DEA’s approval or endorsement of a SOM system is relevant to whether the system complies with those provisions—and thus whether defendants can be held liable under plaintiffs’ tort theories as plaintiffs have framed them.” Dkt. #2725 at p. 17. But the cases they cite for this proposition are entirely distinguishable, as they both deal with the relevance of the FDA’s official approval of drugs to the issue of the effectiveness of those drugs. *See Tobin v. Astra Pharm. Products, Inc.*, 993 F.2d 528, 537-38 (6th Cir. 1993) (finding that FDA’s approval of a drug was relevant in a product-liability case to the issue of whether the drug was effective); *In re Celexa and Lexapro Mktg. and Sales Practices Litig.*, 915 F.3d 1, 5, 10 (1st Cir. 2019) (in “off-label” prescription drug marketing cases, the plaintiffs alleged defendants “engaged in fraud to push their antidepressant drugs on unsuspecting minors for whom the FDA had not approved the use of these medications”; court held that FDA’s prior approval of drug for the treatment of depression in adolescents was relevant to the issue of whether the drug was effective for treating pediatric depression). The FDA has an official process by which it approves drugs. *Celexa*, 915 F.3d at 5. There is no such process for DEA “approval” of SOM programs; indeed, the DEA has expressly disclaimed the notion that it ever “approves” a particular registrant’s SOM program. Dkt. #2652 at pp. 12-13.

Next, in their response, Defendants cite to a 1998 letter from the DEA’s Chief of Liaison and Policy Section to AmerisourceBergen’s predecessor purporting to “pre-approve” its SOM program prior to such program even being implemented. Dkt. #2725 at pp. 17-18.⁶ But this letter

⁶ Plaintiffs explained the irrelevance of this document in their Consolidated Reply Memorandum in Further Support of Plaintiffs’ Motions for Partial Summary Adjudication with Respect to the Controlled Substances Act. Dkt. #2545 at pp. 49-50.

provides no evidence as to whether AmerisourceBergen's SOM program, *as implemented*, violated the CSA and its implementing regulations, which is the relevant issue in this case. Moreover, a DEA official cannot authorize what the law does not sanction or permit,⁷ and Defendants (including AmerisourceBergen) are expected to know their legal obligations under the CSA and cannot rely on the statements of government agents that are contrary to law. Dkt. #2652 at pp. 12-13, 16-17. This is true regardless of whether the DEA official or agent was acting within his official government capacity. *Id.*

Defendants argue that precluding them “from offering evidence showing that DEA approved defendants’ SOM systems . . . would unfairly restrict [their] ability to defend themselves.” Dkt. #2725 at p. 18. Not so. Defendants are welcome to argue and submit evidence to try to prove that their implementation of their respective SOM programs complied with the CSA and its implementing regulations. However, the statements of individual DEA agents purporting to “approve” or “endorse” a particular Defendant’s SOM program are not official “approvals” or “endorsements” by the DEA. Since the jury is likely to improperly conflate the two, admitting this evidence will unfairly prejudice Plaintiffs. The jury may believe that the DEA has already conclusively determined an issue that the jury is being asked to resolve in this trial (*i.e.*, whether Defendants violated their CSA duties), which is not the case. Additionally, any statements by individual DEA agents that purport to interpret the scope of a registrant’s duties under the CSA in a manner that contradicts this Court’s prior rulings would mislead and confuse the jury. Finally, the case Defendants cite in support of their argument is distinguishable. In *Louzon v. Ford Motor Co.*, 718 F.3d 556 (6th Cir. 2013), the Sixth Circuit reversed an *in limine* ruling because “the district court improperly considered non-evidentiary issues in-limine[.]” *Id.* at 558. The court noted that “a mechanism already exists in civil actions to resolve non-evidentiary matters prior to trial—the

⁷ The Court will instruct the jury on the law in this case, which will include the scope of Defendants’ SOM-related duties under the CSA and its implementing regulations. Statements by DEA officials regarding the scope of the CSA that contradict this Court’s prior legal determinations have no probative value and will unfairly prejudice Plaintiffs and confuse the jury.

summary-judgment motion.” *Id.* at 561. The court discussed cases from its sister circuits on this issue, including one in which the Federal Circuit “reversed a district court after it had ‘essentially converted [a] motion *in limine* into a motion for summary judgment’ ” because, “ ‘[i]n doing so, the [district] court did not allow for full development of the evidence and deprived [the defendant] of an opportunity to present all pertinent material to defend against the dismissal of its inequitable conduct defense.’ ” *Id.* at 561-62 (citation omitted). In other words, by seeking to resolve *non-evidentiary* matters through a motion *in limine*, the district court had deprived the defendant “of the procedural protections that attach at summary judgment.” *Id.* at 561. That is not the case here, where Plaintiffs seek to preclude admission of specific evidence the probative value of which, if any, is substantially outweighed by the risk of unfair prejudice.

Defendants also claim that “evidence of DEA approvals and endorsements is highly relevant to the *intent* elements of plaintiffs’ nuisance, RICO, and OCPA claims[.]” referring specifically to Plaintiffs’ allegations that Defendants violated § 841(a) of the CSA. Dkt. #2725 at pp. 20-21. This argument is entirely without merit. Defendants’ purported belief that they were complying with their CSA duties is not relevant to any of Plaintiffs’ claims. Defendants argue this evidence is “probative of whether defendants knowingly or intentionally distributed controlled substances in a manner that was not authorized under the CSA” because the Sixth Circuit has held that a violation of § 841 is a specific intent crime. The cases Defendants cite for this proposition are factually distinguishable and, regardless, in neither case did the Sixth Circuit state that a violation of § 841(a) requires proof that the defendant knew that it was violating the statute or intended to violate the statute.

Section 841 states: “Except as authorized by this subchapter, it shall be unlawful for any person knowingly *or* intentionally—(1) to manufacture, distribute, or dispense, or possess with intent to manufacture, distribute, or dispense, a controlled substance[.]” 21 U.S.C. § 841(a)(1) (emphasis added). In both cases cited by Defendants the § 841(a) violation at issue was possession of a controlled substance *with intent to distribute*. See *U.S. v. Soto*, 794 F.3d 635, 641–42 (6th Cir. 2015) (defendants convicted of conspiracy to possess cocaine with the intent to distribute or aiding and

abetting possession of cocaine with the intent to distribute); *U.S. v. Pope*, 561 F.2d 663, 665 (6th Cir. 1977) (defendant convicted of possession of controlled substances with the intent to distribute). Notably, possession with intent to distribute requires *both* that the defendant knew he was in possession of a controlled substance *and* that he intended to distribute it.⁸ In the present case, however, the only scienter requirement for the § 841(a)(1) violations alleged against Defendants is that Defendants knew that they were manufacturing or distributing a controlled substance.

In *Soto*, the Sixth Circuit did say that knowingly or intentionally *possessing cocaine with the intent to distribute* in violation of §§ 841(a)(1) and 841(b)(1)(B)(ii)(II) is a specific-intent crime. *Id.* at 659. However, the court immediately clarified what it meant by that statement: “It is a specific-intent crime; the government must prove that the defendants *specifically intended to distribute the drugs*.” *Id.* (emphasis added). The court *never* said that the defendants must have specifically intended to violate the CSA or known that they were violating the CSA. Similarly, in *Pope*, the court held that the specific intent requirement related to the defendant’s intent *to distribute a controlled substance*. 561 F.2d at 665 (district court erred by not instructing jury that “intent to distribute” was an element of the crime because a violation § 841(a)(1) *based on possession with the intent to distribute* “requires both general criminal intent and the specific ‘intent to distribute’ before a violation is proven”).

Defendants cite *U.S. v. Odeh*, 815 F.3d 968 (6th Cir. 2016) for the proposition that “specific intent crimes” require “that a defendant act with the additional ‘purpose of violating the law.’ ” *Id.* at 977 n.3 (quoting *U.S. v. Gonyea*, 140 F.3d 649, 653 (6th Cir. 1998)).⁹ But neither *Odeh* nor *Gonyea* involved the statute at issue in this case (§ 841). See *Odeh*, 815 F.3d at 972, 977 (defendant convicted

⁸ See *Pope*, 561 F.2d at 670 (“The ‘knowingly’ and ‘intentionally’ language in s 841(a) refers to the possessor’s awareness that he is in possession of a controlled substance and not to his intention to distribute the substance sometime in the future. 21 U.S.C. s 841(a)(1) requires both general criminal intent and the specific ‘intent to distribute’ before a violation is proven. . . . [Section] 841(a)(1) ‘is violated only if possession is accompanied both by knowledge of the nature of the act and also by the intent ‘to manufacture, distribute, or dispense.’ ”) (internal citation omitted).

⁹ Notably, in *Gonyea*, the court stated: “Courts *generally* hold that a specific intent crime is one that requires a defendant to do more than knowingly act in violation of the law. The defendant must also act with the purpose of violating the law.” 140 F.3d at 653 (internal citations omitted) (emphasis added)

“for violating 18 U.S.C. § 1425(a), which criminalizes knowingly procuring naturalization contrary to law”; court ultimately deemed it unnecessary to decide whether that statute was a general or specific intent crime); *Gonyea*, 140 F.3d at 650-51 (determining whether bank robbery in violation of 18 U.S.C. § 2113(a) was a general or specific intent crime). Moreover, in *Gonyea*, the Sixth Circuit recognized that the explicit reference to an intent requirement in one subsection of the relevant statute indicated that another subsection of the statute that did not reference intent described a general intent crime:

The second paragraph of § 2113(a), providing that a defendant must act “with intent to commit ... any felony,” explicitly requires the government to prove that the defendant harbored a specific intent. By contrast, the first paragraph is silent insofar as requiring that a defendant act with any intent at all. Because we agree with the Eighth Circuit's conclusion that *Congress showed “careful draftsmanship” by including an intent requirement in the second paragraph, but not the first paragraph, of § 2113(a), we hold that the first paragraph of § 2113(a) describes a general intent crime.*

140 F.3d at 653-54 (internal citations omitted) (emphasis added). The same is true in this case, where § 841(a)(1) distinguishes between unlawful possession, which requires specific intent, and unlawful manufacture or distribution, which is illegal if it was done intentionally *or knowingly*. 21 U.S.C. § 841(a)(1).

Defendants have not cited a single case holding that a person who knowingly manufactures or distributes a controlled substance must know that his conduct violates Subchapter I of the CSA to be held criminally liable, or that any violation of § 841(a)(1) *other* than unlawful possession with the intent to manufacture, distribute, or dispense a controlled substance is a specific intent crime. Indeed, the Sixth Circuit cases that have addressed the issue (cited in Plaintiffs’ Motion, Dkt. #2652 at pp. 18-19 & fns. 15-16) explicitly state the opposite.¹⁰ *See also U.S. v. Green*, 548 F.2d 1261, 1270 &

¹⁰ *See U.S. v. Barnes*, 677 Fed. Appx. 271, 272, 277–78 (6th Cir. 2017) (unpublished) (“Barnes is charged with a *general-intent* crime, the manufacture of marijuana [in violation of § 841(a)(1) and § 841(b)(1)(C)]. General-intent crimes require that a defendant ‘knowingly’ committed the criminal act. *This intent requirement goes to whether the defendant knew he was engaging in the act, not whether the defendant knew that his actions were illegal.* Ignorance of the law is no defense to a general-intent crime. *The defendant's good-faith belief in the legality of his conduct cannot negate an element of the charges.*”) (internal citations omitted) (emphasis added); *U.S. v. Walsh*, 654 Fed. Appx. 689, 692, 697-98 (6th Cir. 2016) (unpublished) (defendant convicted of conspiracy to manufacture marijuana in violation of §§ 841, 846; “[W]hile (footnote continues on next page)

n.4 (6th Cir. 1977) (“In this case, the goal of the alleged conspiracy was the manufacture of a controlled substance as defined by 21 U.S.C. s 841(a)(1). *The express language of this statute fails to make specific intent a mandatory element of the crime.*”; noting that “[t]he disjunctive form is used [in § 841(a)(1)] to make scienter or intent independently sufficient.”) (emphasis added). Moreover, Defendants simply ignore *McFadden v. U.S.*, 135 S. Ct. 2298 (2015), in which the United States Supreme Court confirmed that ignorance of the law is no defense to a violation of § 841(a)(1):

We hold that § 841(a)(1) requires the Government to establish that the defendant knew he was dealing with “a controlled substance.”

That knowledge requirement may be met by showing that the defendant knew he possessed a substance listed on the schedules, even if he did not know which substance it was. Take, for example, a defendant whose role in a larger drug organization is to distribute a white powder to customers. The defendant may know that the white powder is listed on the schedules even if he does not know precisely what substance it is. *And if so, he would be guilty of knowingly distributing “a controlled substance.”*

The knowledge requirement may also be met by showing that the defendant knew the identity of the substance he possessed. Take, for example, a defendant who knows he is distributing heroin but does not know that heroin is listed on the schedules. *Because ignorance of the law is typically no defense to criminal prosecution, this defendant would also be guilty of knowingly distributing “a controlled substance.”*

Id. at 2302, 2304 (internal citations omitted) (emphasis added).

Defendant next claim that “even if Section 841 were not a specific intent crime,” Plaintiffs’ own cases make clear that acting “knowingly” means “ ‘to act with ‘knowledge of the facts that constitute the offense[.]’ ” which in this case is the fact that the opioids were distributed “in a

conspiracy is a specific intent crime, the specific intent required to support a conviction is the intent to achieve the objective of the conspiracy—here, to manufacture 100 or more marijuana plants. *The Government was not required to show that Jenkins knew or, intended to violate, federal drug laws.* “[T]he Supreme Court has identified only a few areas, such as tax law, where ignorance of the law is a defense, and that is because the tax system is so complex.’ The CSA is not such a ‘highly technical statute[.]’ and presents little to no ‘danger of ensnaring individuals engaged in apparently innocent conduct.’ Jenkins argument regarding her purported ignorance of the law is unavailing.” (internal citations omitted) (emphasis added).

manner that was not ‘authorized by’ subchapter I of the CSA.” Dkt. #2725 at p. 21 n.16 (quoting *U.S. v. Fuller*, 162 F.3d 256, 260 (4th Cir. 1998)). But *Fuller* actually states the opposite:

Fuller did not deny either that he knew the drugs he sold to Varner were crack cocaine or that he intended to sell them to Varner. . . . His only defense was a legal one based on his alleged belief that, as mayor of Vance, he was authorized to sell the crack cocaine as part of his investigation. On this basis, he claimed that he never “intend[ed] to violate the criminal laws of the United States” because he lacked “the specific intent to commit those crimes.” *But it is not a requirement of 21 U.S.C. § 841(a) that the defendant have specifically intended to violate the statute in order to be found guilty.* The *mens rea* required by the statute is that the defendant “knowingly or intentionally” engage in the prohibited activities. To act “knowingly” is to act with “knowledge of the facts that constitute the offense” but not necessarily with knowledge that the facts amount to *illegal* conduct, unless the statute indicates otherwise. *Since nothing in the text of 21 U.S.C. § 841(a) indicates that Congress meant to punish only those defendants who actually intended to violate the statute, Fuller’s admission that he was aware that he was selling crack cocaine to Varner is all that was required to prove that his conduct was knowingly carried out.* And to commit an act intentionally is to do so deliberately and not by accident. Fuller admitted that he deliberately sold the crack cocaine to Varner.

162 F.3d at 260 (internal citation omitted) (emphasis added).

Finally, Defendants argue that “unlike the CSA’s prohibition of cultivating marijuana, the provisions that defendants are accused of violating are highly technical, and thus plaintiffs must prove that defendants were aware of the specific ‘duties’ they allegedly violated.” Dkt. #2725 at p. 21 n.16 (citing *U.S. v. Tobin*, 676 F.3d 1264, 1282 (11th Cir. 2012)). Again, *Tobin*, which involved prescription drugs and not marijuana, actually states the opposite: “[W]e do not see the CSA as the sort of technical statute that requires the government to prove that ‘the defendant was aware of the duty at issue.’ ” 676 F.3d 1264, 1280 n.6. *See also* Dkt. #2652 at p. 19 n.17.¹¹ Moreover, the statutory language of § 841(a)(1) does not make any distinction between the necessary *mens rea* for

¹¹ Defendants ignore the portion of *Tobin* that discusses the required state of mind under § 841(a)(1) itself, and instead cites the portion of the opinion discussing the required state of mind under 21 C.F.R. § 1306.04(a), which “authorizes the distribution of controlled substances by a practitioner so long as the prescription is ‘issued for a legitimate medical purpose [and] in the usual course of [the practitioner’s] professional practice.’ ” *Tobin*, 672 F.3d at 1282 (quoting 21 C.F.R. § 1306.04(a)). Under that particular regulation, which is not at issue in the present case, a doctor’s subjective belief is relevant to the question of whether he issued the prescription for a legitimate medical purpose. *Id.* at 1281-82.

manufacturing marijuana and manufacturing or distributing opioids. 21 U.S.C. § 841(a)(1). The relevant question is whether Defendants knowingly or intentionally manufactured or distributed the controlled substance. As discussed above and in Plaintiffs' Motion (Dkt. #2652 at pp. 17-19), § 841(a)(1) does not require that Defendants know that they were manufacturing or distributing controlled substances in violation of the CSA.

16. Any suggestion or argument that the DEA's failure to sanction or initiate enforcement actions against a particular Defendant demonstrates a determination by the DEA that the Defendant complied with the CSA or its implementing regulations, or gives rise to a presumption that Defendants complied with same.

Defendants claim that the "weight of authority holds that the absence of a pertinent regulatory enforcement action is admissible[.]" citing three cases. Dkt. #2725 at p. 22. But these cases are factually distinguishable. In *Cummins v. BIC USA, Inc.*, 727 F.3d 506 (6th Cir. 2013), the plaintiff sued a cigarette lighter manufacturer for violations of Kentucky's Consumer Protection Act and the federal Consumer Product Safety Rule. *Id.* at 509. The plaintiff lost at trial and, on appeal, argued that the district court erred in allowing the defendant "to introduce evidence of the failure of the Consumer Product Safety Commission to take action concerning the lighter [at issue]." *Id.* The plaintiff's sole argument against the admission of this evidence was a statute (15 U.S.C. § 2704(b)) that stated that the failure of the CPSC "to take any action or commence a proceeding with respect to the safety of a consumer product shall not be admissible in evidence in litigation at common law or under state statutory law relating to such consumer product." *Id.* at 509, 511, 514 n.3. The appellate court held that the admission of this evidence in that case was not error because the statute was "intended 'to exclude those instances where the CPSC had completely failed to act, as opposed to those instances where the CPSC engaged in activity that ultimately led to a decision not to regulate.'" *Id.* at 514 (citation omitted). The court agreed, however, that such evidence "would not be conclusive of liability" and instructed the jury accordingly. *Id.* at 511-12, 514 ("[T]he district court clearly instructed the jury that the CPSC's failure to cite BIC for violating product safety rules was merely a factor to be considered and not determinative in relation to either of plaintiff's claims.").

In *In re Cook Med., Inc., IVC Filters Mktg., Sales Practices and Prod. Liab. Litig.*, 114ML02570RLYTAB, 2018 WL 6617375 (S.D. Ind. Dec. 18, 2018), which involved product liability claims, the court held that evidence that the product “was never recalled by the FDA, that the FDA never observed any violations of [the defendant’s] quality system during its inspections between 2000 and 2014, and that the FDA never used any enforcement action against [the defendant]” was “relevant to [the defendant’s] defenses—that is [sic] design and development decisions regarding the [product] were reasonable and that its product is safe.” *Id.* at *2. In *Eagle Oil & Gas Co. v. Travelers Prop. Cas. Co. of Am.*, 7:12-CV-00133-O, 2014 WL 3744976 (N.D. Tex. July 30, 2014), the court permitted the plaintiffs’ expert “to testify regarding whether an enforcement action was brought against [p]laintiffs[.]” but would “not allow [the expert] to invade the province of the jury by telling the jury what result to reach or to give legal conclusions.” *Id.* at *12. Notably, the plaintiffs represented that they were not presenting this expert “for any opinions on the ultimate issue of this case, namely, [p]laintiffs’ compliance with reasonable prudent operator standards.” *Id.*¹²

At most, Defendants’ cases held that the fact of agency inaction, in and of itself, was relevant to the particular claims asserted in those actions. But Plaintiffs’ claims in the present action do not implicate the statutory provisions at issue in *Cummins*, nor are they the same type of claims at issue in *Eagle* or *Cook*. Regardless, even if evidence of the mere fact that the DEA or FDA did not sanction or initiate enforcement actions against a particular Defendant is admissible, Defendants provide no legal authority whatsoever suggesting that such evidence demonstrates a determination by the agency, or gives rise to a presumption, that Defendants complied with their statutory and regulatory obligations. There are many reasons that the DEA or FDA may have failed to act that have nothing to do with the lawfulness of Defendants’ conduct, including the agency’s limited resources and the Defendant’s concealment of its conduct. Thus, Defendants, their counsel, and their witnesses

¹² See also *id.* (“Plaintiffs further assert it is a question of fact as to whether Eagle Oil was cited by the Railroad Commission for any violations of Rule 3.13, and [the expert] can answer such question without providing any opinions on how this relates to Plaintiffs’ compliance with reasonably prudent operator standards.”).

should be precluded from making any such suggestion or argument that agency inaction is an indication of agency approval. And to the extent the Court permits Defendants to adduce evidence of agency inaction, Plaintiffs request that the jury be instructed that such evidence is not determinative in relation to any of Plaintiffs' claims. *Cf. Cummins*, 727 F.3d at 511-12, 514.

17. **Any suggestion or argument that the FDA's failure to sanction or initiate enforcement actions against a particular Defendant demonstrates a determination by the FDA that the Defendant complied with the Federal Food, Drug, and Cosmetic Act or FDA regulations, or gives rise to a presumption that Defendants complied with same.**

Defendants' arguments against Plaintiffs' MIL No. 17 are based on the same three cases they cite with respect to Plaintiffs' MIL No. 16, and should be rejected for the same reasons discussed above. *Supra* at § 16.¹³ Defendants also cite *Mahaney ex rel. estate of Kyle v. Novartis Pharm. Corp.*, 835 F. Supp. 2d 299 (W.D. Ky. 2011), *order vacated in part on reconsideration sub nom. Mahaney on behalf of estate of Kyle v. Novartis Pharm. Corp.*, 1:06-CV-00035-R, 2012 WL 12996015 (W.D. Ky. Jan. 4, 2012), as a case in which the court held that the absence of FDA sanctions was admissible. Specifically, the court held that such evidence was relevant and probative of the defendant drug manufacturer's defenses in a product-liability case based on its failure to warn of a drug's dangers and side effects, noting that "other courts have used compliance with the FDA as proof of due care by a pharmaceutical company." 835 F. Supp. 2d at 303, 320-21. But Plaintiffs are not asserting negligence claims in this trial.

18. **Any reference that any award of damages will adversely affect the ability of any member of the jury to purchase, or have available medications in the future, or affect the cost thereof, or have an adverse effect on the drugs or health products available to individuals or industries in the United States or elsewhere (*e.g., argument or testimony that if Plaintiffs are awarded damages, the cost of medicines or medical care will increase, or that medications will no longer be available*).**

¹³ Although *Cook* involved the admissibility of FDA inaction, the issue in that product-liability case was whether the defendant had acted reasonably in *designing* the allegedly defective product. 2018 WL 6617375, at *2. In the present case, on the other hand, Plaintiffs have asserted claims against the Manufacturer Defendants based on their false and deceptive marketing of opioids.

Defendants concede that personalizing their arguments to members of the jury is inappropriate. Dkt. #2725 at p. 25. They object to the remainder of Plaintiffs' MIL No. 18 for three reasons, all of which are without merit.

First, they claim this evidence would be relevant to punitive damages if Plaintiffs were to pursue such a claim at trial. Plaintiffs have already stated that they no longer intend to assert a claim for punitive damages in this trial, which Defendants acknowledge in their response. *Id.* at p. 26. This argument against MIL No. 18 is therefore moot.

Defendants next claim that this MIL "is so broad that it appears to sweep in evidence that is relevant to liability[.]" such as "evidence of the availability of 'drugs . . . to individuals,' including whether legitimate pain patients are being denied legitimate opioid prescriptions by doctors," which they argue, "is relevant to whether there is a public nuisance." *Id.* at p. 26. Plaintiffs dispute that such evidence is at all relevant to the existence of a public nuisance. Regardless, Defendants are ignoring the first part of Plaintiffs' MIL, which seeks to preclude "[a]ny reference *that any award of damages will . . . have an adverse effect on* the drugs . . . available to individuals." (emphasis added). This type of argument encourages members of the jury to decide the case based on improper factors rather than the evidence presented at trial. The potential future implications of a damage award against Defendants have no bearing on the questions the jury will be answering in this case: (i) whether Defendants' conduct renders them liable under theories of public nuisance, RICO, OCPA, and/or civil conspiracy; and, if so, (ii) the amount of damages that will adequately compensate Plaintiffs for their harm that was caused by Defendants' wrongful conduct.

Finally, Defendants argue that this MIL is inappropriate because "it is unclear what plaintiffs will argue at trial." Dkt. #2725 at p. 26. They make no effort to identify any argument Plaintiffs could possibly make at trial that would open the door to the type of evidence sought to be excluded by Plaintiffs' MIL No. 18. And if, during the trial, they believe that Plaintiffs have "opened the door" to this evidence, they have every right to make that argument to the Court. Plaintiffs simply ask that such argument be made outside the presence of the jury unless and until the Court deems such evidence admissible.

19. **Any suggestion or indication that a judgment in this case will have an adverse effect on the finances or ability of Defendants to compete in the marketplace, or that it may negatively affect the economy or lead to layoffs (*e.g., any argument or testimony that a judgment in this or any other case might force the company to lay off employees, or cut back on its business, or affect the local or other economy*).**

Contrary to Defendants' assertions, Plaintiffs are not seeking to preclude Defendants from providing a general background of their businesses. As with their opposition to Plaintiffs' MIL No. 18, Defendants ignore the first part of MIL No. 19 which seeks to preclude "[a]ny suggestion or indication *that a judgment in this case will have an adverse effect on the finances or ability of Defendants to compete in the marketplace, or that it may negatively affect the economy or lead to layoffs[.]*" (emphasis added). As discussed above (*supra* at § 18), this type of argument encourages members of the jury to decide the case based on improper factors rather than the evidence presented at trial. The potential future implications of a damage award against Defendants have no bearing on the questions the jury will be answering in this case: (i) whether Defendants' conduct renders them liable under theories of public nuisance, RICO, OCPA, and/or civil conspiracy; and, if so, (ii) the amount of damages that will adequately compensate Plaintiffs for their harm that was caused by Defendants' wrongful conduct. Finally, Plaintiffs are no longer pursuing punitive damages, so Defendants' arguments regarding the relevance of this evidence to a punitive damage claim are moot.

20. **Any reference that a verdict for Plaintiffs will adversely impact pharmaceutical manufacturers' incentive or ability to develop new drugs.**

Defendants' arguments against Plaintiffs' MIL No. 20 are without merit for the same reasons discussed above with respect to Plaintiffs' MIL No. 18. *Supra* at § 18.

21. **Any reference to or suggestion that Defendants and the pharmaceutical industry have to factor in the overall cost of lawsuits when determining the cost of their products to the public (*e.g., argument or testimony that lawsuits and claims force companies to charge more for their products*).**

Defendants state they have "no plans to offer evidence about the impact that lawsuits have on the pricing of pharmaceuticals," but claim Plaintiffs' MIL No. 21 should be denied as premature because Plaintiffs may "make arguments at trial that implicate this question – *e.g.*, by arguing that this litigation will make medical care more affordable or accessible[.]" to which Defendants "must be

permitted to respond.” Dkt. #2725 at p. 29.¹⁴ Plaintiffs have no intention of making any such argument. If, during the trial, Defendants believe that Plaintiffs have somehow “opened the door” to this evidence, they have every right to make that argument to the Court. Plaintiffs simply ask that such argument be made outside the presence of the jury unless and until the Court deems such evidence admissible.

22. Any reference to deposition or trial testimony derived from witnesses produced only in litigation in which Plaintiffs did not participate, other than testimony that has been produced to Plaintiffs during discovery in this MDL that may be offered for impeachment purposes.

There are at least three grounds for the Court to exclude reference to witness testimony from other cases where Plaintiffs were not parties and that was not produced during discovery, only one of which Defendants even address, albeit incorrectly, in their opposition.

First, a witness’s prior testimony in another case generally is inadmissible hearsay unless the witness is unavailable in the current case. FED. R. EVID. 804(b) (“The following are not excluded by the rule against hearsay *if the declarant is unavailable as a witness*: (1) Former Testimony”) (emphasis added); *see also* FED. R. CIV. P. 32(a)(1)(B) (“At a hearing or trial, all or part of a deposition may be used against a party on these conditions: . . . (B) it is used to the extent it would be admissible under the Federal Rules of Evidence *if the deponent were present and testifying*”) (emphasis added). Defendants barely acknowledge this requirement, *see* Dkt. #2725 at p. 31 (“Rule 804(b)(1) recognizes a hearsay exception for deposition testimony from unavailable witnesses”), and do not establish that any witness whose prior testimony they seek to introduce was or is unavailable to

¹⁴ The cases cited by Defendants to support their argument are distinguishable. *See William F. Shea, LLC v. Bonutti Research, Inc.*, 2:10-CV-00615-GLF, 2013 WL 2424382, at *2 (S.D. Ohio June 4, 2013) (court denied defendant’s motion to preclude plaintiff’s experts “from testifying to (1) legal conclusions concerning disputed contracts and (2) personal views on the weight of the evidence” because defendant’s arguments were “premature and, in any event, fail to show that the experts have impermissibly gone beyond the bounds of proper expert testimony in their depositions”); *AUSA Life Ins. Co. v. Dwyer*, 899 F. Supp. 1200, 1201-02 (S.D.N.Y. 1995) (court denied plaintiffs’ motion to exclude expert’s report as premature where the parties had “not yet completed expert depositions, much less trial preparation”).

testify in this case. Absent this showing, no prior testimony is admissible under either FED. R. CIV. P. 32 or FED. R. EVID. 804.

Second, even assuming unavailability, the party against whom prior testimony is offered must have had, either directly or indirectly through a “predecessor in interest,” the “opportunity and similar motive to develop [the former testimony] by direct, cross-, or redirect examination.” FED. R. EVID. 804(b)(1)(B). Defendants contend that this requirement is satisfied with respect to prior testimony in the Oklahoma state-court opioid litigation because “that testimony was subject to cross-examination by a party with interests identical to [P]laintiffs’ interests” Dkt. #2725 at p. 29. This argument is incorrect.

The Sixth Circuit and this Court have excluded prior testimony where the party against whom it is offered was not a party and did not have a predecessor-in-interest as a party in the prior case to develop the prior testimony in accordance with its interests. *See Murphy v. Owens-Illinois, Inc.*, 779 F.2d 340, 344 (6th Cir. 1985); *In re Polyurethane Foam Antitrust Litig.*, 2015 U.S. Dist. LEXIS 183454, at *46 (N.D. Ohio March 6, 2015). Defendants attempt to satisfy this requirement by relying on cases holding that it suffices for an unrelated party in the prior case to have had a “like motive to cross-examine about the same matters as the present party would have” Dkt. #2725 at p. 31 (quoting *Clay v. Johns-Manville Sales Corp.*, 722 F.2d 1289, 1295 (6th Cir. 1983)). The *Clay* decision is inapposite, however, because the witness in question had passed away and thus was “unavailable” for the second trial. 722 F.3d at 1294.¹⁵ No such showing is made here.

Third, and most fundamentally, even where the Sixth Circuit has looked to mere commonality of litigation interest to assess a current party’s opportunity to develop prior testimony through a predecessor party, it also has held that introduction of the prior testimony must not be unfairly prejudicial under FED. R. EVID. 403. *See Dykes v. Raymark Indus., Inc.*, 801 F.2d 810, 817 (6th

¹⁵ Defendants also rely for this argument on *New Jersey Tpk. Auth. v. PPG Indus., Inc.*, 197 F.3d 96 (3d Cir. 1999). Dkt. #2725 at p. 30. The *PPG* case likewise recognized that “[i]n order for former testimony to be admissible under Rule 804(b)(1) . . . the declarant must be unavailable” 197 F.3d at 110.

Cir. 1985) (“What is more important, however, is the question of potential prejudice that can accrue to a [party] against whom a deposition is introduced which the [party] never had an opportunity to adequately refute.”). Defendants completely ignore this consideration in their opposition.

Plaintiffs would be unfairly prejudiced by introduction of Oklahoma state-court litigation testimony because they not only were not parties to that action, *but they also did not have access to that testimony until well after the close of discovery in this case.* Dkt. #1118 (Discovery Ruling No. 9) at p. 2 (“[P]laintiffs are not entitled to testimony or statements given after January 25, 2019, which is the discovery cut-off date for the MDL Track One cases.”). This means that regardless of which party had what interests in the Oklahoma case, Plaintiffs here would be unfairly prejudiced because they had no understanding of the Oklahoma case testimony or ability to respond to it through discovery in this action. *Cf. Saturn Mfg., Inc. v. Williams Patent Crusher & Pulverizer Co.*, 713 F.2d 1347, 1357 (8th Cir. 1983) (“It is evident that the movie was first discovered during the second week of trial and thus there was no adequate opportunity for the opposing side to conduct an investigation. The district court excluded the movie, observing that ‘there must be some point at which we get too deep into the ambush.’ We agree that the movie posed a substantial danger of prejudice, and, accordingly, find no abuse of discretion in its exclusion.”).

Indeed, earlier rulings in this action anticipated and ameliorated just this type of prejudice by making clear that the parties would not be permitted to ambush one another at trial with evidence that was not produced in discovery. *See, e.g.*, Dkt. #606 (Discovery Ruling No. 1) at p. 6 (“When Plaintiffs later seek to prove causation or damages at trial, whether through expert testimony regarding a statistical model or otherwise, Plaintiffs may not rely affirmatively or defensively on evidence or data they did not produce during discovery.”); Dkt. #1027 (Discovery Ruling No. 5) (“[I]f any plaintiff expert or defense expert relies on any specific prescriptions, or specific persons who obtained prescriptions, those prescriptions and persons must be identified with specificity in the expert’s disclosure and should also be identified to opposing counsel *substantially before the deadline for non-expert discovery.*”) (emphasis added). Since Defendants did not identify the Oklahoma case testimony until after the close of discovery, they cannot now introduce it at trial.

In sum, the Court should prohibit Defendants from introducing prior witness testimony that they did not produce until after the close of discovery because this is both inadmissible hearsay and unfairly prejudicial to Plaintiffs.

23. Any argument or suggestion that the “learned intermediary” doctrine limits the liability of any Defendant or absolves any Defendant from liability.

Defendants offer the following justification to invoke the “learned intermediary” doctrine: “A jury could find that because a physician is obligated to know the risks of the medicines she prescribed as a learned intermediary – not any misrepresentations by defendants – caused plaintiffs alleged harms.” Dkt. #2725 at p. 32. In other words, by using the term “learned intermediary,” Defendants hope to conjure in the minds of the jury an obligation on the part of medical professionals to see through Defendants’ false and misleading marketing practices and protect society from Defendants’ misdeeds. If Defendants wish to assert such a causation defense, however, they must find some other doctrine to support it. The “learned intermediary” doctrine does not require prescribers to ferret out a drug manufacturer’s lies.

Instead, the learned intermediary doctrine applies in a personal injury or product defect case against a drug manufacturer which has given adequate information about the drug to the prescribing medical professional. *See* OHIO REV. CODE. ANN. §2307.76(C); *Seley v. G.D. Searle & Co.*, 423 N.E.2d 831 (Ohio 1981). “The learned intermediary doctrine does not relieve the manufacturer of liability to the ultimate user for an inadequate or misleading warning; it only provides that the warning reaches the ultimate user through the learned intermediary.” *Vaccariello v. Smith & Nephew Richards, Inc.*, 763 N.E. 2d 160, 164 (Ohio 2002).

Therefore, the learned intermediary doctrine is inapplicable here because Plaintiffs are *not* the ultimate users of the drugs; the claims are *not* for personal injury; and the claims are *not* based on a failure to warn the drugs’ ultimate users directly. Defendants cite no authority applying the doctrine in a case such as this. The sole authority they do cite, *Harris v. Purdue Pharma, L.P.*, 218 F.R.D. 590 (S.D. Ohio 2003), has no bearing here. The claims in *Harris* were for personal injury, brought as a class action. The *Harris* court considered the learned intermediary doctrine only as part of its

analysis of the individualized matters the personal injury plaintiffs would be required to prove and their implications for the commonality requirement for class certification. *Id.* at 596. Here Plaintiffs' claims do not require proof of the individualized matters identified in *Harris*, nor is the commonality analysis applicable to this non-class action.

The "learned intermediary" doctrine has no application to this litigation, and any suggestion or argument otherwise can only serve to confuse or mislead the jury.

24. Any reference to, or evidence of, any alleged "failure to mitigate" by Plaintiffs.

There are at least four grounds for the Court to exclude reference to or evidence of any alleged "failure to mitigate" by Plaintiffs, none of which Defendants refute.

First, as Defendants recognize, the duty to mitigate does not require Plaintiffs to incur extraordinary or unreasonable expenses. *See, e.g., Chicago Title Ins. Co. v. Huntington Nat'l Bank*, 719 N.E.2d 955, 961-62 (Ohio 1999). Defendants argue that whether expenses are reasonable or extraordinary is itself a question of fact for the jury. Dkt. #2725 at p. 34. That generally is the rule under Ohio law. *See, e.g., Telecom Acquisition Corp. I, Inc. v. Lucic Enterprises, Inc.*, 62 N.E.3d 1034, 1050 (Ohio Ct. App. 2016). However, Ohio courts also recognize that "whether a party . . . used 'reasonable efforts' . . . becomes a question of law when reasonable minds can come to but one conclusion." *Interstate Gas Supply, Inc. v. Callex Corp.*, No. 04AP-980, 2006 WL 328679, at *5 (Ohio Ct. App. Feb. 14, 2006). That is the case here. Plaintiffs' evidence shows that they have suffered hundreds of millions of dollars in damages (and face far greater-still abatement costs going forward). Dkt. #2577 (Op. and Order Denying Motion to Exclude McGuire) at p. 2. No reasonable mind could conclude that Plaintiffs should have expended these enormous sums to mitigate the harms Defendants created. For this reason alone, the Court should exclude any reference to mitigation.

Second, there also is no duty to mitigate where the defendant had the same opportunity to minimize damages that the plaintiff did. *See Chicago Title*, 719 N.E.2d at 962. Defendants answer that this rule applies only where a defendant could have minimized damages by performing the same act that the plaintiff could have. Dkt. #2725 at p. 34 (citing *State ex rel. Stacy v. Batavia Loc. Sch. Dist.*

Bd. of Educ., 829 N.E.2d 298, 311 (Ohio 2005)). Even if so, Defendants’ blanket assertion that they cannot be said to have had an equal opportunity “to provide the governmental services that form the basis of [P]laintiffs’ damages claims,” Dkt. #2725 at p. 34, sweeps too broadly. One of the primary services at issue is treatment for the widespread drug addiction caused by Defendants’ unlawful promotion and distribution conduct. Dkt. #2577 (Op. and Order Denying Motion to Exclude McGuire) at p. 5 n.4-5. Defendants, prescription drug manufacturers or distributors all, may well have been able to provide or else fund these types of services just as the Plaintiff Counties do.

Third, there also is no duty to mitigate harms caused by intentional misconduct. Defendants cite a single case in concluding that “Ohio courts have roundly rejected this approach” Dkt. #2725 at p. 35 (citing *Chicago Title Ins. Corp. v. Magnuson*, 2009 WL 3321372 (S.D. Ohio Oct. 9, 2009)). The Court should reject this sweeping conclusion both because the authority cited is not controlling, and because courts elsewhere that apply the rule governing intentional misconduct do so for reasons that are consistent with principles of Ohio law. In *Warner/Elektra/Atlantic Corp. v. County of DuPage*, 991 F.2d 1280 (7th Cir. 1993), the court addressed an inverse condemnation claim based on flooding damage, held that a duty to mitigate applied because the claim was grounded in negligence, but recognized with respect to the plaintiff’s alleged failure to mitigate that, under applicable Illinois law, “such contributory or comparative negligence would not be a defense, in whole or in part, to an intentional tort.” *Id.* at 1287 (citing *Burke v. 12 Rothschild’s Liquor Mart, Inc.*, 593 N.E.2d 522 (Ill. 1992)). Ohio law is exactly the same on this point. *See, e.g., Lambert v. Shearer*, 616 N.E.2d 965, 970 (Ohio Ct. App. 1992) (“[C]ontributory negligence and comparative negligence are no defense to a reckless or intentional tort.”). Thus, to the extent that an alleged failure to mitigate harm is deemed a species of contributory negligence, it has no application here to Plaintiffs’ claims based upon Defendants’ intentional wrongdoing.

Fourth, the Plaintiff County Governments have no duty to mitigate for Defendants’ fraudulent conduct. Defendants recognize this rule’s application in federal False Claims Act cases. Dkt. #2725 at p. 35; *see also United States v. United Techs. Corp.*, 950 F. Supp. 2d 949, 954 (S.D. Ohio

2013) (“The Government has no duty to mitigate damages in fraud actions, including those under the FCA.”) (quoting *United States ex rel. Monahan v. Robert Wood Johnson Univ. Hosp. at Hamilton*, 2009 WL 4576097, at *8 (D.N.J. Dec. 1, 2009)). Defendants err, however, in seeking to limit this rule to a single statute and to the U.S. Government alone. Dkt. #2725 at p. 35 (“Nor have courts extended this exception to other governmental entities . . .”). In *City of New York v. FedEx Ground Package System, Inc.*, 314 F.R.D. 348 (S.D.N.Y. 2016), the court held that no duty to mitigate applied to claims under the federal Contraband Cigarette Trafficking Act (“CCTA”) that were brought by the State and City of New York because the State and City’s “fundamental role as discretionary enforcer of the public interest when suing under the CCTA precludes application of a duty to mitigate damages.” *Id.* at 358. Although the court also left open whether any duty to mitigate would apply to the State and City’s RICO claims, it recognized that “the fact that Plaintiffs rely on CCTA violations as their RICO predicate suggests the very same problems as requiring mitigation of damages for the CCTA claim itself.” *Id.* at 359. The same conclusion should apply here to the Plaintiff Counties’ RICO and OCPA claims predicated upon Defendants’ violations of the federal Drug Abuse Prevention and Control Act.

Defendants are wrong to claim that an isolated decision in *New Mexico v. Gen. Elec. Co.*, 335 F. Supp. 2d 1185 (D.N.M. 2004), stands for the rule that “government plaintiffs are regularly required to mitigate damages[.]” Dkt. #2725 at p. 35. First, Defendants do not suggest that the State in that case raised any of the arguments made here, and the circumstances were quite different. There, the court applied New Mexico state law and held that where the State plaintiff indicated no intent to mitigate hazardous waste contamination of groundwater and had not proven that most or all of the groundwater source was affected, the State “may *not* recover monetary damages for present and future value of the use of groundwater that in fact has not been or need not be lost.” 335 F. Supp. 2d at 1231 (emphasis in original). This decision thus addressed a lack of proof of damage that was separate and distinct from any mitigation issue, and which is not presented here. Finally, Defendants’ mitigation argument here is, effectively, an attempt to call into question local governments’ allocation of resources or efforts on behalf of the public to address harm created by

others (here, namely, Defendants). Courts have repeatedly rejected such arguments, whether as the basis for liability claims, or raised under the guise of mitigation. As the Ohio Supreme Court has explained:

It is most often asserted that because the available public resources are limited by the resources possessed by the community, the deployment of them must remain in the realm of policy decision. Obviously, there are insufficient police resources to meet every need, particularly in high crime areas and during times of higher crime rates. Police departments must be able to prioritize and create responses without the benefit of hindsight.

Sawicki v. Village of Ottawa Hills, 525 N.E.2d 468, 476–79 (Ohio 1988) (applying the “public duty doctrine” to claims negligence claims against a local government and explaining that “[o]ne of the basic policy considerations has been that of finance”); *see also Est. of Graves v. Circleville*, 902 N.E.2d 535, 541–44 (Ohio App. 4th Dist. 2008) (explaining that the doctrine remains in force following statutory changes impacting sovereign immunity), *aff’d and remanded*, 922 N.E.2d 201 (Ohio 2010); *see also Resolution Tr. Corp. v. Gibson*, 829 F. Supp. 1103, 1107-08 (W.D. Mo. 1993) (striking mitigation defense from answer and stating that the “court is persuaded . . . that public policy weighs in favor of the public not bearing the risk for errors in judgment made by the RTC”).

For any or all of the reasons set forth, the Court should prohibit Defendants from referencing or introducing evidence of any alleged “failure to mitigate” by Plaintiffs.

PLAINTIFF-SPECIFIC LIMINE REQUESTS

- 25. Any reference to, or evidence of, the identities of any children, including but not limited to children in child protective custody.**

While Defendants appear to recognize the appropriateness of protecting the identities of children, their suggestion that the Court’s order *in limine* be restricted to the actual names of children not otherwise in the public record is inadequate. Obviously there are numerous other specific identifiers (*e.g.*, social security numbers, addresses, names of parents or guardians), that could divulge a child’s identity. Moreover, simply because a child’s name or identifying information is in some public record does not mean it is appropriate to place that child’s information in the record of a

highly publicized and closely watched trial. Plaintiffs believe that the standard proposed in their Motion, that evidence that would potentially reveal the identity of any child be excluded at trial, will protect children's identities without interfering in any way with Defendants' ability to present their case.

26. Any reference to, or evidence of, any individually identifiable health information or medical records related to any individual patients, including but not limited to information or records that identifies babies with neonatal abstinence syndrome or persons with opioid use disorder.

Plaintiffs' requested MIL No. 26 was carefully crafted to protect the privacy of individual identifiable medical information without compromising Defendants' ability to present relevant evidence at trial. Plaintiffs do not seek by this MIL to exclude evidence of treatment or services to individuals, simply to exclude individually identifiable medical information. Defendants do not appear to resist this objective, but instead propose that the issue be addressed as and when it arises. Plaintiffs do not believe that such a piecemeal approach is efficient or appropriate. Plaintiffs do not anticipate any material disagreement regarding what constitutes individually identifiable medical information, and in the unlikely event such a disagreement arises, the Court will be in a position to determine quickly whether any particular evidence is covered by the order the Plaintiffs request.

27. Any reference to, or evidence of, the identity of any undercover law enforcement personnel who may be called to testify at trial.

Plaintiffs' requested MIL No. 27 seeks narrow relief with respect to deposition testimony Defendants may offer from undercover law enforcement officers, specifically that the testimony be read to the jury, that a pseudonym be substituted for the officer's name and that information that could personally identify the officer, such as address, description or employment history, not be allowed.

In their response, Defendants cite criminal cases that involve excluding the public from portions of a criminal trial and other significant procedural steps taken by some courts to protect law enforcement officer identities. *See Ayala v. Speckard*, 131 F.3d 62 (2d Cir. 1997); *U.S. v. Maso*, 07-10858, 2007 WL 3121986 (11th Cir. Oct. 26, 2007) (per curiam); *Rodriguez v. Miller*, 537 F.3d 102 (2d

Cir. 2008). The principal relief sought here, substituting a pseudonym when the officer's testimony is read, provides no meaningful concerns regarding either the confrontation clause nor the public's right to attend the trial. Defendants know the true names of the witnesses and have had the opportunity to take their depositions. The public will continue to have access to the trial, the only information it was not receive is the identity of the undercover law enforcement officer, a matter as to which there is an obvious and important interest in preserving confidentiality.

Nor will Defendants be prejudiced by this relief. Contrary to Defendants' assertion, the substitution of pseudonyms will not constitute special treatment of these witnesses that may cause the jury to accord their testimony added weight. Rather, the jury will have no reason to know the substitution occurred. To the extent documents that contain an officer's name are to be used, the pseudonym can be substituted in those documents as well. Any inconvenience resulting from this is far outweighed by the benefit of continuing the ability of these law enforcement officers to function undercover.

28. Any reference to deaths of individuals while in the Cuyahoga County Jail or in the custody of the Cuyahoga County Sheriff's Office, and any reference to the U.S. Marshalls Service report on jails.

Plaintiffs will address Defendants' responses to Plaintiffs' MIL Nos. 28-33 collectively below. *Infra* at § 33.

29. Any reference to or allegation of current or former government corruption in Cuyahoga County.

Plaintiffs will address Defendants' responses to Plaintiffs' MIL Nos. 28-33 collectively below. *Infra* at § 33.

30. Any reference to grand jury testimony or proceedings involving Cuyahoga County.

Plaintiffs will address Defendants' responses to Plaintiffs' MIL Nos. 28-33 collectively below. *Infra* at § 33.

31. Any reference to recent investigations or subpoenas involving Cuyahoga County.

Plaintiffs will address Defendants' responses to Plaintiffs' MIL Nos. 28-33 collectively below. *Infra* at § 33.

32. Any reference to the indictment of Ken Mills, former director of Cuyahoga County jails.

Plaintiffs will address Defendants' responses to Plaintiffs' MIL Nos. 28-33 collectively below. *Infra* at § 33.

33. Any reference to any investigations of former Cuyahoga County Sheriff Pinkney or the Cuyahoga County Sheriff's Office.

Defendants' opposition to Plaintiffs' MIL Nos. 28-33 demonstrates how Defendants hope to have it both ways—by being allowed to introduce evidence that is wholly irrelevant while preventing Plaintiffs from using evidence of Defendants' *relevant* bad acts. Defendants argue that Plaintiffs' MIL Nos. 28, 29 and 33 should be denied as overly broad, while MIL Nos. 30, 31 and 32 are somehow equivalent to Distributor Defendants' Motion No. D-3, which seeks to exclude evidence of the indictment of David Gustin, the former compliance officer for McKesson's warehouse in southern central Ohio. The Court should grant Plaintiffs' MIL Nos. 28-33 and prevent Defendants from prejudicing the jury by introducing irrelevant information on alleged problems within the Cuyahoga County government.

These MILs are not overly broad, making Defendants' citation to *Sperberg v. Goodyear Tire*, 519 F.2d 708, 712 (6th 1975), inapposite. Instead, MIL Nos. 28- 33 seek to prevent potential jury confusion and the waste of trial time on evidence that is clearly irrelevant. For example, the U.S. Marshalls Service report does not discuss opioids or substance abuse issues at the jail. *See* Plaintiffs' MIL No. 28, Dkt. #2652 at p. 36. Similarly, the indictment of Ken Mills (Plaintiffs' MIL No. 32), and the facts underlying it, which are wholly unrelated to opioids or substance abuse at the jail, are irrelevant and will only serve to waste valuable trial time and possibly distract the jury from focusing on the issues they need to determine. Dkt. #2652 at p. 38. Allegations of current or former

government corruption in Cuyahoga County (Plaintiffs' MIL No. 29) also bear no relationship to opioids or drug abuse. Dkt. #2652 at pp. 36-37.

Defendants advocate for a general rule that would exclude evidence of criminal indictments and investigations if there is no final judgement, while allowing the facts related to those indictments and investigations to be admitted whether they are relevant or not. (*See* Dkt. #2725 at pp. 43-44, arguing that the court should grant Distributor Defendants' Motion No. D-3). This would serve their purpose of excluding evidence of relevant conduct while allowing them to prejudice the jury with information on issues in the Cuyahoga County government that have nothing to do with opioids or the damages that the County is claiming. Mr. Gustin's conduct is clearly relevant to the issues at the heart of this case, including whether McKesson complied with its duties under the CSA. In contrast, Plaintiffs' MILs seek to exclude conduct that is plainly unrelated to any relevant issues. Defendants' opposition is devoid of any facts related to government corruption (Plaintiffs' MIL No. 29), grand jury proceedings (Plaintiffs' MIL No. 30), recent investigations or subpoenas involving Cuyahoga County (Plaintiffs' MIL No. 31), the indictment of Ken Mills (Plaintiffs' MIL No. 32) and investigations of evidence of or reference to any investigations of former Cuyahoga County Sheriff Pinkney or the Cuyahoga County Sheriff's Office (Plaintiffs' MIL No. 33) that involve opioids or drug abuse. Nor have they specified how any of these issues demonstrate that the County caused or contributed to its damages.

Defendants' untimely addition to Defendants' Joint Witness List illustrates their purpose to distract the jury with irrelevant nonsense. Defendants identified Gary Brack as a fact witnesses who "is expected to testify concerning his duties and responsibilities as Interim Director of Ambulatory Care at Cuyahoga County Jail and related to his previous relevant employment." Dkt. #2742 at p. 10, ¶ 4.¹⁶ Mr. Brack recently filed a whistleblower lawsuit against Cuyahoga County Executive

¹⁶ Plaintiffs have objected to testimony from Mr. Brack as a witness Defendants failed to disclose during the discovery period. *See* Plaintiffs' Objections to Defendants' Witness List, Dkt. #2749 at p. 2. Because Mr. Brack was not disclosed during the discovery period, and because his testimony is irrelevant as indicated here, the Court should bar his testimony and strike him from the witness list. Plaintiffs did not include Mr. Brack in their initial Motions *in Limine* because they had no indication that he could be called (footnote continues on next page)

Armond Budish alleging that Mr. Brack was terminated for speaking out about conditions, unrelated to the opioid epidemic, at the Cuyahoga County Jail. Mr. Brack has not participated as a witness in this case either via written interrogatory responses or through a deposition. Defendants seek to introduce his testimony solely to try to prejudice the jury against Cuyahoga County for reasons unrelated to the claims or defenses in this litigation. As with MIL Nos. 28-33, Mr. Brack's testimony should be excluded in its entirety under Rules 401, 402, and 403 because it is irrelevant to the jury questions on liability and damages, has no probative value, and would create a significant danger of unfair prejudice, confusing the issues, and misleading the jury. Permitting Mr. Brack's testimony likely would force Plaintiffs to have to introduce evidence rebutting his allegations, thereby distracting the jury from the issues that need to be resolved now and wasting valuable time in what is already going to be a complex and lengthy trial.

Similarly, permitting evidence of non-opioid related issues, whether they have resulted in a conviction of anyone associated with the Cuyahoga County government or not, will waste time and distract the jury. The basis for Plaintiffs' MIL Nos. 28-33 is to avoid that by seeking to exclude non-opioid and non-drug related information about the Cuyahoga County government as irrelevant and prejudicial under Rules 401, 402 and 403. The Court should grant these MILs and order that any evidence about the Cuyahoga County government, and the specific issues raised in MIL Nos. 28-33, is excluded from trial as irrelevant and likely to unfairly prejudice Plaintiffs and sidetrack the jury and waste time at trial.

34. Any reference to any "podcast" or other media coverage regarding Cuyahoga County courts.

Defendants argue that Plaintiffs' MIL No. 34 should fail because Plaintiffs have not identified any specific statement that should be excluded. Their opposition misses the point, which is to ensure the exclusion of evidence of any podcasts or media coverage of the Cuyahoga County

as a witness.

courts that are unrelated to the issues in this case. Media coverage of alleged issues with the Cuyahoga County courts, such as the *Serial* podcast, is completely separate from whether Defendants' conduct caused Cuyahoga County's damages. These stories may also be sensationalized and lack indicia of reliability. For these reasons, they should be excluded under Rules 401, 402 and 403. These statements are also inadmissible hearsay under Rule 802. *See Noonan v. Norris*, 594 F.3d 592, 603 (8th Cir. 2010) ("Newspaper articles are 'rank hearsay.'") (quoting *Miller v. Tony & Susan Alamo Found.*, 924 F.2d 143, 147 (8th Cir. 1991)).

Moreover, in their response, Defendants reveal their plan to attempt to introduce statements made by the County's employees or agents that "suggest" other causes of increased drug offenses in the County's court system, or on any issue in this case, as a party admission, regardless of their reliability or relevance. Notably, Defendants fail to identify these alleged County employees or agents, the alleged statements and in what specific fora the statements were made. Defendants cannot introduce random statements made in response to questions outside the context of this litigation and deem them party admissions. Rule 801(d)(2) includes a scope requirement that only allows statements to be non-hearsay admissions if they were "made by the party's agent or employee *on a matter within the scope of that relationship and while it existed.*" FED. R. EVID. 801(d)(2)(D) (emphasis added). Courts routinely reject statements made by employees or alleged agents that were outside the scope of that relationship or without proof that the employee or agent could bind the party. *See, e.g., Cary v. Cordish Co.*, 731 F. App'x 401, 406 (6th Cir. 2018); *Huffman v. Speedway LLC*, 621 F. App'x 792, 799 (6th Cir. 2015); *United States v. Wiedyk*, 71 F.3d 602, 605–06 (6th Cir. 1995). Moreover, the term "suggest" is so broad and vague that it allows virtually any statement to qualify. The Court should grant Plaintiffs' MIL No. 34 and exclude evidence of or reference to any podcast or other media coverage regarding the Cuyahoga County courts that is not relevant to any issue to be decided in this case or if made by a person unauthorized to speak for the County. This includes statements

made by the County's alleged employees or agents that "suggest" other causes of increased drug offenses in the County's court system or comment on this litigation.¹⁷

35. Any reference to any investigation regarding the death of Aniya Day Garrett.

Defendants seek to introduce evidence regarding Aniya Day Garrett's death even though Defendants concede her death "did not involve opioids." Dkt. #2725 at p. 45.¹⁸ Although Defendants concoct a theory that such evidence is relevant because it "contradicts [P]laintiffs' damages experts, who simply attribute all . . . increases [in costs to Cuyahoga County Children and Family Services (CFS)] to the opioid crisis" (Dkt. #2725 at p. 45), this theory is simply incorrect. Plaintiffs' experts carefully detailed the complex models that they used to identify the increased costs to CFS that are attributable to Defendants' misconduct. While it is certainly true that "[s]everal of [P]laintiffs' experts opine that increased CFS and related costs borne by [P]laintiffs in recent years are the result of the opioid crisis" (*id.*), neither Plaintiffs nor their experts claim, as Defendants assert, "that *all* increased costs to CFS in recent years are due to the opioid crisis – full stop – without any consideration of other potential causes." *Id.* at p. 46 (emphasis added). For instance, the report of Professor McGuire, a Professor of Health Economics in the Department of Health Care Policy at Harvard Medical School,¹⁹ makes clear that his analysis has been careful to identify

¹⁷ At a minimum, if Defendants seek to introduce this evidence, the Court should order that Defendants must identify the statements and witnesses outside the presence of the jury so that the Court can determine if the witness was authorized to speak for the County, if the statements were within the scope of the witness's relationship with the County, and evaluate the relevance and potential prejudice of any such statements. If admitted, the person would have to be called as a witness and given a chance to explain the statements and context.

¹⁸ Defendants initially listed Mickhal Garrett, Aniya's father, as a trial witness (Dkt. #2642 at pp. 13-14), but they then removed him from their Amended Witness List. Dkt. #2742. Garrett's lawyer stated that his client's inclusion on Defendants' witness list was "puzzling," and declared, "There's no evidence that opioids played any role in any way shape or form [f]or what happened to 4-year-old Aniya." See <https://www.cleveland.com/court-justice/2019/10/drug-companies-may-probe-cuyahoga-county-jail-problems-mothers-murder-of-4-year-old-daughter-at-october-opioid-trial.html> (last visited Oct. 7, 2019). It is unclear, then, which witness Defendants intend to use to introduce evidence about Aniya Day Garrett's death, but in any event, such evidence should be excluded.

¹⁹ Dkt. #1899-16 at ¶ 1.

those increased costs to CFS (and other divisions in Cuyahoga and Summit Counties) *that are attributable to Defendants' misconduct*.²⁰ Similarly, Professor Cutler, a Professor of Applied Economics at Harvard,²¹ focused his analysis on assessing the share of various harms imposed on county divisions that is attributable to Defendants' misconduct.²² Given that Plaintiffs and their experts have *not* purported to claim that *all* increased costs for CFS are directly attributable to the opioid crisis or to Defendants' misconduct, it is unremarkable that Cynthia Weiskittel, Director of Cuyahoga County CFS, testified that other matters have also resulted in additional costs to CFS. Contrary to Defendants' assertion, Ms. Weiskittel's testimony in no way contradicts the opinions of Plaintiffs' experts.

Under these circumstances, the tragic death of Aniya Day Garrett, which Defendants concede had nothing to do with opioids or any other drug, is irrelevant to the issues in this case and should be excluded for that reason alone. FED. R. EVID. 401. Alternatively, what little probative value such evidence may have is far outweighed by the prejudice to Cuyahoga County that such evidence would pose. FED. R. EVID. 403.

36. Any reference to or allegation of current or former government corruption in Summit County.

Defendants' objection makes clear that any evidence of or reference to allegations of current or former government corruption in Summit County is not relevant to any issue to be decided in

²⁰ *E.g., id.* at ¶¶ 16-18 (explaining model for determination of increased costs to Bellwether divisions "that is attributable to defendants' misconduct"); ¶ 72 (describing methodology for attribution of share of harms due to defendants' misconduct and showing percentages for CFS ranging from 1.0% in 2006 to 7.5% in 2018).

²¹ Dkt. #1899-4 at ¶ 1.

²² *Id.* at ¶ 9 ("My analysis yields annual estimates of the share of various harms imposed on selected departments in each Bellwether government . . . that is attributable to defendants' misconduct."); ¶¶ 118-119 (expressing share of harms attributable to defendants' misconduct in formulaic terms); ¶ 120 (for Cuyahoga Sheriff Division, identifying "share of crime attributable to opioids" as 5.5%, but showing "share of crime attributable to defendants' misconduct" as either 1.2% or 2.0%, depending on which of two approaches is utilized); ¶ 123 (percentages of harm to CFS due to defendants' misconduct for each year between 2006 and 2018, ranging from low of 1.0% to high of 7.6%).

this case. They suggest they might conceive of a hypothetical in which such evidence could be relevant, but do not actually contend that their hypothetical could apply. Moreover, the only conceivable evidence they might introduce would be precisely the kind that they concede “would *not* be relevant.” Dkt. #2725 at p. 48 (emphasis in original) (citing embezzlement from a high school sports fund). Here, the only potential evidence of which the County is aware concerns a dispute over \$2,300 in spending on newsletters that had nothing to do with opioids and purportedly did not have a public benefit, a matter which is currently under dispute, as the County contends that the expenditure was valid, and which has nothing to do with opioids or any issues in this case. Further, Defendants offer nothing to counter the County’s Rule 403 arguments; rather, they ask the court to ignore them as too “vague.” Dkt. #2725 at p. 48. Thus, there is no meaningful dispute that any probative value is substantially outweighed by the danger of unfair prejudice, confusing the issues, and misleading the jury. *See Doe v. Claiborne County*, 103 F.3d 495, 515 (6th Cir. 1996) (unfair prejudice is “the undue tendency to suggest a decision based on improper considerations”).

37. Any reference to deaths of individuals while in the Summit County Jail or in the custody of the Summit County Sheriff’s Office.

Here too, Defendants’ objection makes clear that any evidence of or reference to jail issues in Summit County unrelated to the substance/opioid abuse, including any reference to deaths or other incidents involving individuals while in the Summit County Jail or in the custody of the Summit County Sheriff’s Office is not relevant to any issue to be decided in this case. Attempting to manufacture a theory of relevance, Defendants argue that they may seek to introduce “evidence of the County’s failure to provide adequate care or screening for opioid addiction in the jail and to prevent County-employed guards from smuggling opioids to inmates.” Dkt. #2725 at p. 43.²³ They do not, however, suggest that such evidence actually exists. Likewise, they fail to explain how or why they would need to take the further step of introducing evidence of the deaths sought to be

²³ As explained in Plaintiffs’ separate reply regarding mitigation, this is not a valid defense, and any evidence offered to dispute mitigation is inadmissible in any event.

excluded. In this regard, they effectively concede that evidence of deaths unrelated to opioids should be excluded. Defendants' opposition confirms that their sole purpose in trying to elicit such information would be to attempt to prejudice the jury against Summit County for reasons that are unrelated to the matters at issue in this case, as well as that, assuming *arguendo* any relevance, any probative value is substantially outweighed by the danger of unfair prejudice, confusing the issues and misleading or inflaming the jury. This evidence must be excluded under Rules 401, 402, and 403. Further, Defendants' opposition confirms that they may seek to use such evidence to cast aspersions on the County's character generally, which is also inadmissible under Rule 404.

Dated: October 14, 2019

Respectfully submitted,

/s/Paul J. Hanly, Jr.

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CERTIFICATE OF SERVICE

I certify that the foregoing instrument was served via the Court's ECF system to all counsel of record on October 14, 2019.

/s/ Peter H. Weinberger
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